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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,567	10/15/2003	Mark G. Frei	011738.00135	7143

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EXAMINER

KOWALEWSKI, FILIP A

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary

Application No.

10/687,567

Applicant(s)

FREI ET AL.

Examiner

Filip A. Kowalewski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Fig. 5 – 501; Fig. 10 – 1009, 1027; Fig. 11 – 1009; Fig. 12 – 24; Fig. 14 – 1430, 1435; Fig. 15 – 1501, 1519; Fig. 16 – 1600; Fig. 19 – 1911; Fig. 20 - 2001. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 15, 16, 29, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which applicant regards as the invention. The term "detection cluster" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984). Claims 2-28, 41 and 42 are rejected due to their dependence upon claims 1, 15, 16, 29, and 40.

The term "meaningfully" in claim 1 is a relative term which renders the claim indefinite. The term "meaningfully" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. In the present case, it is indefinite what data applicant considers to be meaningful. Claims 2-38 are rejected due to their dependence upon claim 1.

Claims 2, 3, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "statistically meaningful data" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537

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(Bd. App. 1984). Claims 34, 41, and 42 are rejected due to their dependence upon claims 2 and 40.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "blanking hardware" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "blanking software" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

The term "approximately" in claims 17, 18, and 19 is a relative term which renders the claim indefinite. The term "approximately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one

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of ordinary skill in the art would not be reasonably appraised of the scope of the invention. In the present case, it is indefinite what the exact duration of the time intervals is claimed.

The term "approximately" in claim 20 is a relative term which renders the claim indefinite. The term "approximately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. In the present case, the relation between the ratio and the short-term value is indefinite.

The term "short-term" in claims 20 and 21 is a relative term which renders the claim indefinite. The term "short-term" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. In the present case, it is indefinite what duration of time is meant by "short-term".

The term "long-term" in claims 20 and 22 is a relative term which renders the claim indefinite. The term "long-term" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. In the present case, it is indefinite what duration of time is meant by "long-term".

Claims 26, 27, 28, 41, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "maximum ratio" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984). Claims 29-32, 38, 39 are rejected due to their dependence upon claims 26 and 27.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "first number" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "second number" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite

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since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "third number" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "fourth number" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. The term "treatment therapy unit" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984). Claims 41 and 42 are rejected due to their dependence upon claim 40.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "meaningful information" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-43 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,016,449 to Fischell et al. (hereinafter Fischell).

Fischell discloses the following claim limitations:

- 1. A method for treating a patient for a nervous system disorder, the method comprising:**
 - (a) receiving a neurological signal through a monitoring element and an amplifier, wherein the neurological signal is a member of a set of neurological signals (Col. 13 – Ln. 39-42);**
 - (b) detecting, by a detection algorithm, a first detection cluster based upon the neurological signal (Col. 13 – Ln. 43-45);**
 - (c) in response to (b), delivering a treatment therapy through a delivery unit during a first time interval (Col. 13 – Ln. 46-51);**
 - (d) in response to (b), blanking the neurological signal during the first time interval of time (Col. 13 – Ln. 52-55);**
 - (e) blanking the neurological signal during a second time interval, wherein the neurological signal is adversely affected by a prior treatment therapy (Col. 13 – Ln. 52-55);**
 - (f) processing the neurological signal during a third time interval until the detection algorithm meaningfully represents a post-treatment brain state (Col. 13 – Ln. 56-62);**
and
 - (g) determining whether to redeliver the treatment therapy using an algorithm output that meaningfully represents the post-treatment brain state (Col. 13 – Ln. 39-42).**

2. The method of claim 1, further comprising: (h) subsequent to (g), processing the neurological signal during a fourth time interval in order to obtain statistically meaningful data about a subsequent time period (Col. 13 – Ln. 56-62).

3. The method of claim 2, further comprising: (i) determining whether to redeliver the treatment therapy based upon the statistically meaningful data about the neurological signal obtained from processing during the fourth time interval (Col. 13 – Ln. 39-42 & Ln. 56-62).

Claims 4, 5, and 6 are rejected on substantially the same basis as claim 1.

7. The method of claim 6, wherein the at least one time interval is determined from an analysis of the neurological signal in relation to at least one factor selected from the group consisting of the treatment therapy, a noise level, and a duration of amplifier saturation (Col. 13 – Ln. 46-51).

8. The method of claim 1, wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a mental health disorder, and a psychiatric disorder (Col. 13 – Ln. 36-38).

9. The method of claim 8, wherein the nervous system disorder is selected from the

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group consisting of epilepsy (Col. 13 – Ln. 36-38), Parkinson's disease, essential tremor, dystonia, multiple sclerosis (MS), anxiety, a mood disorder, a sleep disorder, obesity, and anorexia.

10. The method of claim 1, wherein the treatment therapy is selected from the group consisting of electrical stimulation, magnetic stimulation, drug infusion, and brain temperature control (Col. 13 – Ln. 46-51).

11. The method of claim 1, wherein the neurological signal is selected from the group consisting of an electrical signal, a chemical signal, a biological signal, a temperature signal, a pressure signal, a respiration signal, a heart rate signal, a pH-level signal, and a peripheral nerve signal (Col. 13 – Ln. 39-42).

12. The method of claim 1, wherein the monitoring element is selected from the group consisting of an electrode and a sensor (Fig. 1 – 15a-n electrodes).

13. The method of claim 1, wherein the treatment therapy is provided to a location of a body selected from the group consisting of a brain, a cranial nerve, a spinal cord, and a peripheral nerve (See Fig. 1).

14. The method of claim 1, wherein the medical device system is selected from the group consisting of an external system, a hybrid system, and an implanted system (See

Fig. 1).

15. The method of claim 1, further comprising: (h) detecting a subsequent detection cluster through the amplifier and the monitoring element; and (i) repeating (b)-(g) (Col. 13 – Ln. 39-65).

16. The method of claim 1, further comprising: (h) processing the neurological signal for a fifth time interval, wherein a subsequent detection cluster is not detected; (i) at a subsequent time after the fifth time interval, detecting the subsequent detection cluster; and (j) repeating (b)-(g) (Col. 13 – Ln. 39-65).

17. The method of claim 1, wherein the second time interval is approximately three seconds (Col. 19 – Ln. 3-23).

18. The method of claim 1, wherein the third time interval is approximately two seconds (Col. 19 – Ln. 3-23).

19. The method of claim 1, wherein the fourth time interval is approximately one half of a second (Col. 19 – Ln. 3-23).

20. The method of claim 1, wherein the monitoring element comprises an electrode array, and wherein (b) comprises: (i) determining a ratio that is associated with each

electrode of the electrode array, wherein the ratio approximately equal to a short-term value of an associated neurological signal divided by a long-term value of the associated neurological signal; and (ii) determining one of the ratios that is larger than the other ratios (Col. 14 – Ln. 16-50).

21. The method of claim 20, wherein the short-term value is selected from the group consisting of a short-term average and a short-term median data point (Col. 16 – Ln. 43-53).

22. The method of claim 20, wherein the long-term value is selected from the group consisting of a long-term average and a long-term median data point (Col. 16 – Ln. 43-53).

Claims 23 and 24 are rejected on substantially the same basis as claim 1.

25. The method of claim 1, further comprising: (h) blanking a second neurological signal during the second time interval, wherein the second neurological signal is affected by the signal artifact (Col. 13 – Ln. 52-55).

26. The method of claim 1, further comprising: (h) if a maximum ratio of the set of neurological signals is always as great as a predetermined threshold during the third interval and the fourth interval, stimulating the patient subsequent to the fourth interval

(Col. 13 – Ln. 43-51).

27. The method of claim 1, further comprising: (h) if a maximum ratio of the set of neurological signals is less than a predetermined threshold during the third interval and the fourth interval, preventing a stimulation of the patient until an occurrence of a subsequent seizure detection (Col. 13 – Ln. 43-51).

28. The method of claim 27, wherein the subsequent seizure detection occurs when the maximum ratio is always as great as a predetermined threshold during a duration constraint (Col. 13 – Ln. 43-51).

29. The method of claim 26, wherein a number of allowable stimulations per detection cluster is limited to a first number (Col. 13 – Ln. 46-51).

30. The method of claim 26, wherein a number of allowable stimulations per seizure detection is limited to a second number (Col. 13 – Ln. 46-51).

31. The method of claim 26, wherein a number of allowable stimulations per hour is limited to a third number (Col. 13 – Ln. 46-51).

32. The method of claim 26, wherein a number of allowable stimulations per day is limited to a fourth number (Col. 13 – Ln. 46-51).

In regard to claims 33-39, Fischell discloses the above disclosed method and computer-executable instructions (Col. 14 – Ln. 17-49)

40. An apparatus for treating a patient for a nervous system disorder, the apparatus comprising:

a treatment therapy unit that delivers treatment therapy to the patient (Fig. 2 – 40 stimulation subsystem);

a set of monitoring elements that obtains a set of neurological signals (Fig. 2 – 15a-n electrodes); and

a processor (Fig. 2 – 50 central processor) that is coupled to the treatment therapy unit and the set of monitoring elements, wherein the processor is configured to perform:

(a) receiving a neurological signal through a monitoring element and an amplifier, wherein the neurological signal is a member of a set of neurological signals (Col. 13 – Ln. 39-42);

(b) detecting, by a detection algorithm, a first detection cluster based upon the neurological signal (Col. 13 – Ln. 43-45);

(c) delivering a treatment therapy through a treatment therapy unit during a first time interval (Col. 13 – Ln. 46-51);

(d) in response to (b), blanking the neurological signal during the first time interval of time (Col. 13 – Ln. 52-55);

(e) blanking the neurological signal during a second time interval, wherein the neurological signal is affected by a signal artifact and wherein the amplifier is stabilizing (Col. 13 – Ln. 52-55);

(f) processing the neurological signal during a third time interval in order to stabilize the detection algorithm (Col. 13 – Ln. 56-62); and

(g) in response to (e), processing the neurological signal for a fourth time interval in order to obtain statistically meaningful data about a subsequent time period (Col. 13 – Ln. 56-62).

41. The apparatus of claim 40, wherein the processor is configured to perform: (h) if a maximum ratio of the set of neurological signals is always as great as a predetermined threshold during the third interval and the fourth interval, stimulating the patient subsequent to the fourth interval (Col. 13 – Ln. 43-51).

42. The apparatus of claim 40, wherein the processor is configured to perform: (h) if a maximum ratio of the set of neurological signals is less than a predetermined threshold during the third interval and the fourth interval, preventing stimulating the patient until an occurrence of a subsequent seizure detection (Col. 13 – Ln. 43-51).

43. A method for treating a nervous system disorder, the method comprising:

(a) receiving a neurological signal through a recording or sensing element (Col. 13 – Ln. 39-42);

(b) detecting, changes in the neurological signal through a detection algorithm
(Col. 13 – Ln. 43-45);

(c) in response to (b) delivering a therapy through a delivery unit for a pre-specified duration (Col. 13 – Ln. 46-51);

(d) in response to (b), blanking the neurological signal during a delivery of therapy (Col. 13 – Ln. 52-55);

(e) blanking the neurological signal for an additional time interval after a termination of the delivery of therapy, to allow for amplifier recovery (Col. 13 – Ln. 52-55); and

(f) resume processing of the neurological signal immediately after completion of (d) and (e) for a shortest time interval required to obtain meaningful information about a post-treatment status of the signal (Col. 13 – Ln. 56-62).

Conclusion

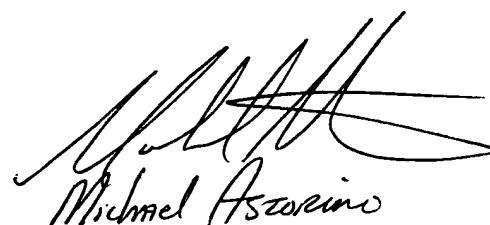
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Filip A. Kowalewski whose telephone number is 571-272-5668. The examiner can normally be reached on Monday - Friday: 8am - 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FAK
October 2, 2006



Michael Ascareino

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/26/2004; 6/10/2004; 11/23/2004.